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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,763	11/15/2001	Corey M. Crafton	1533.1940002/MAC/MBT	7167

45453 7590 06/28/2005

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EXAMINER	
KAUSHAL, SUMESH	
ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No. 09/987,763	Applicant(s) CRAFTON ET AL.	
	Examiner Sumesh Kaushal Ph.D.	Art Unit 1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 May 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2,4-22 and 25-38*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Sumesh Kaushal

SUMESH KAUSHAL
PATENT EXAMINER

Continuation of 5. Applicant's reply has overcome the following rejection(s):

Prior art rejection of claim 24 (claim 24 canceled). Written description rejection of claims 1, 24-22 and 25-38.

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 1-2, 4-22 and 25-38 stand rejected under 35 U.S.C. 101 regarding lack of a specific asserted utility or a well-established utility and under 35 USC 112(1) regarding enablement issues for the reasons of record as set forth in the office action mailed on 3/24/05

Applicant's arguments filed regarding lack of utility and enablement issues have been fully considered but they are not persuasive.

TABLE 1A

Nucleotide sequences that can be used to regulate gene expression

Seq. I.D. NO:	Gene*	Regulatory Molecule‡
1	pta	acetate
2	aceA	acetate
3	aceB	acetate
4	adh	ethanol
5	aldB	ethanol
6	poxB	pyruvate
7	ldh	pyruvate
8	amyB	carbon
9	malZ	carbon
10	bglX	carbon
11	gam	carbon
12	glgX	carbon
13	hisD	histidine
14	pyrR	pyrimidine
15	purD	purine
16	hrcA	temperature
17	htpX	temperature
18	dnaK	temperature
19	ctc	temperature
20	grpE	temperature
21	clpB	temperature
22	narA	oxygen

Sequence I.D. NOs 1, 2, and 3 have been previously described. The remaining sequences were discovered in ADM's *Corynebacterium glutamicum* genome sequencing project.
*Putative genes regulated by sequence I.D. NOs 4–22 were determined by homology to genes identified in other organisms, e.g., *Escherichia coil* or *Bacillus subtilis*.
‡Putative regulatory molecules associated with the regulatory regions of SEQ I.D. NOs 4–22 were determined by analogy to regulatory regions identified in other organisms.

As stated earlier the specification fails to meet utility requirements regarding specific asserted utility or a well-established utility for the nucleotide sequences of SEQ ID NO:7.

At best the specification asserts that the nucleotide sequences of SEQ ID NO:7 is a ***putative ldh-like*** *gene* that is regulated by pyruvate. *See table 1A*

However, the specification fails to provide any evidence which establishes that the SEQ ID NO:7 encodes a *ldh-like* responsive element that is regulated by pyruvate.

The applicant argues that the only one credible assertion of utility is necessary and office fails to establish that invention lacks a prima facie lack of utility.

The applicant argues that regulation of transcription of a reporter gene like β-galactosidase in a bacterial host cell is a well-established and specific asserted utility. This is found not persuasive because non-specific regulation of a reporter gene like β-gal is not a specific asserted-utility and is not considered as a well-established utility.

The applicant argues that the specification discloses use of a polypeptide including the nucleotide of SEQ ID NO:7 to regulate expression of ldh as shown in table 1A. However, applicant's argumetns are found NOT persuasive because the specification fails to provide any evidence which establishes that the SEQ ID NO:7 encodes a Ldh-like responsive element that is regulated by pyruvate.

The applicant argues that give the referenced homology of Table-1A, one skilled in the art might reasonably exprect the sequence of invention to have credible utility as probes for structures with equivalent functions. However, applicant's argumetns are found not persuasive because a probe in general is not considred have a credible utility, unless it is any specific diagnostic value. In addition the specificaiton as filed fails to provide any sequcnece comparision that established any homology to a known ldh motifs.

The applicant furhter argues that it is difficult ot under stand the meaning of statement *"Even though the specification asserts that the SEQ ID NO:7 encodes a Ldh like responsive element that is regulated by pyruvate, the specification as filed fails to disclose that nucleic acid sequences of SEQ ID NO:7 capable of regulating the transcription of a reporter gene in response to pyruvate (see table 1A)"*. However, this statement could be best understood in view of applicant's own remarks which states "the specification discloses use of a polynucleotide including the nucleotide sequence set forth in SEQ ID N0; 7 to regulate expression of ldh (as shown in Table IA)", especially in view of fact that the specification fails to provide any evidence, which establish that the SEQ ID NO:7 encodes a Ldh-like responsive element that is regulated by pyruvate.

Furthermore, It is noted that patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable (*See Brenner v. Manson, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966), Stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."*) Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. Therefore, the asserted use for the claimed invention is not supported by either a specific and/or substantial utility, since no function can be ascribed to the nucleic acid sequence as claimed (*see Revised Interim Utility Guidelines*). The only immediate apparent utility for the instant invention would be further scientific characterization of the claimed nucleic acid sequences a putative pyruvate responsive transcriptional element.